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ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Continuation Sheet for Advisory Action

Continuation of Box 3. The proposed amendments will not be entered because they introduce numerous new limitations that have not been considered or searched by the examiner, e.g. “for immediate dispersion to a graft site on a patient” and “split or full thickness skin tissue sample.” These limitations would require more than the cursory review permitted after final rejection. The amendments also propose to add four new claims without canceling at least four finally rejected claims.

Continuation of Box 11. The request for reconsideration has been fully considered, but it does NOT place the application in condition for allowance.

As an initial matter, the finality of the 7/9/10 Office action was proper because although the words "keratinocyte basal cells, melanocytes, and fibroblasts" appeared in the 10/19/09 claims, those claims did not actually require the sample to contain all three types of cells. The 10/19/09 claims required that the composition comprise a ratio of these cells “comparable” to the ratio found in a skin sample, but the claims set forth no basis for comparison and did not actually require that the skin sample be one that contained all three. The 4/29/10 amendments require the composition to comprise these three cell types, not just to have “a ratio” of the cell types that is somehow “comparable” to the “ratio” in another sample. For further discussion of the limitation in question, see the 12/30/09 Office action at page 4 (rejecting the claim because the limitations did not place metes and bounds on the composition). In the interest of compact prosecution, the examiner granted applicant the courtesy of interpreting the claims favorably for art

rejection purposes. (12/30/09 Office action, page 5.) By applicants' rule, an examiner complying with the Office's policy favoring compact prosecution could never make an Office action final.

The 9/9/10 claims have not been entered, but the remarks submitted therewith are not persuasive of error. Applicant alleges that M.P.E.P. § 2111.02 regards the preamble and therefore "is not applicable to applicants' claims," which is confusing because the intended use "for immediate dispersion to a graft site" in claim 29 indeed appears in the preamble. Such functional limitations do not affect the structure and physical properties of the composition. While describing a product in terms of its function is not itself improper (see *In re Swinehart*, 439 F.2d 210, 169USPQ 226 (CCPA 1971)), claims directed to a product should be distinguished from the prior art product in terms of structure rather than function; this point was recently revisited. "When a claim limitation is defined in purely functional terms, the task of determining whether that limitation is sufficiently definite is a difficult one that is highly dependent on context (e.g., the disclosure in the specification and the knowledge of a person of ordinary skill in the relevant art area). We note that the patent drafter is in the best position to resolve the ambiguity in the patent claims, and it is highly desirable that patent examiners demand that applicants do so in appropriate circumstances so that the patent can be amended during prosecution rather than attempting to resolve the ambiguity in litigation." *Halliburton Energy Services, Inc. v. M-I LLC*, 85 USPQ2d 1654, 1663 (Fed. Cir. 2008). While functional claiming is authorized by 35 U.S.C. § 112, sixth paragraph, that statute was enacted specifically to preclude overly broad claims that effectively purport to cover

any and all limitations, so long as they perform the required functions. Specifically, claims that are ambiguous as to boundaries for functional limitations may be indefinite and do not distinguish the claimed product over the prior art. It is not clear which cell suspensions made using the steps of claim 29 would be suitable "for immediate dispersion to a graft site on a patient" and which would not. For this reason, the intended use limitation has no clear patentable weight. Applicant appears to be attempting to claim within the product claim a method of using that product, which is improper. Applicant's comments about the handling of *in vitro* samples relative to those intended for application at page 17 are not supported by evidence, and there is no clear relationship between a propensity toward "pathogen contamination" and the claimed composition. If applicants' composition has reduced susceptibility toward contamination, the claims should so recite in a manner that limits the structure.

Applicant's arguments about the dermal-epidermal junction are not clearly relevant to the patentability of the claimed composition. The claims require beginning with a tissue sample that contains dermis, epidermis, and the junction (step (a)), but this is an inherent property of skin; in fact, step (b) recited in claim 29 only requires harvesting cells from the dermis and the epidermis. The "wherein" limitations at the end of claim 29 provide the only structural requirements for the claimed composition: The lack of xenogenic serum, a particular maximum congregate size, and a requirement for three types of cells to be present. Applicant has provided no evidence that any of the steps are critical to obtaining a composition with those properties.

Furthermore, applicant's arguments about Baur's teachings appear to be based on an assumption that Baur has discarded the dermal-epidermal junction, but this is not positively recited in the reference and not supported by evidence. Baur teaches separating the dermis from the epidermis, then processing the portions. There is no clear reason to presuppose that the junction is not included in at least one of these samples. The absence of a statement that Baur's method retains the junction cannot be interpreted as evidence that the junction must necessarily have been discarded. Applicant's statement at page 17 that Baur's cell composition "would still be inherently different from those [cells] harvested at the dermal-epidermal junction" has no basis in evidence, and in any case, the claims do not require such a harvest. This point also addresses applicants' argument about product-by-process limitations -- applicant has provided no evidence that the steps recited in claim 29 yield a product materially different from that of Baur. See M.P.E.P. § 2113.

Applicants' argument about Baur's use of serum are not germane to the rejection of record because Baur's NR-3 medium is "fully defined," i.e. free of serum. See page 22, line 5. Therefore, Baur's Example 3 teaches a serum-free suspension of cells. As above, there is no evidence that the manner in which the cells are obtained has any material effect on the resulting composition. Applicant has provided no comparison between cells isolated using serum-free medium and then further cultured in that medium and cells isolated using serum-free medium and then further cultured in serum-free medium. See M.P.E.P. § 2113.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is (571)272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/
Primary Examiner, Art Unit 1651